DEPARTMENT OF HEALTH & HUMAN SERVICES

94985d
Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

July 29, 2004

Ref: 2004-DAL-26

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joe Nottenkamper, Owner
298 Brock Road
Beebe, Arkansas 72012

Dear Mr. Nottenkamper:

A tissue residue report received by the Food and Drug Administration (FDA) from the United States Department of Agriculture (USDA) reported the presence of an illegal drug residue in a cow that originated from your farm. As a follow-up to USDA's finding, our investigators performed an investigation of your cattle farm located at 298 Brock Road, Beebe, AR, on April 16, 2004. The investigation confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act. On March 9, 2004 you sold a cow, identified with a back tag number [redacted] at [redacted] USDA Est. [redacted] a USDA inspected slaughter house in [redacted]. The cow carcass and parts were condemned based upon the USDA analysis (Laboratory Report # 00378520) of tissue samples collected from that animal which revealed the presence of 18 ppm, 13 ppm and 22 ppm of oxytetracycline, in the kidney, liver and muscle tissues, respectively. The presence of this drug in edible tissues from this animal at these levels causes the food to be adulterated. 21 CFR 556.500 establishes a tolerance for oxytetracycline of 12 ppm in the kidney, 6 ppm in the liver and 2 ppm in the muscle of the uncooked edible tissues of cattle.

A food is also adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health." As it applies to this case "insanitary conditions" means that you hold animals which are offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply.

For example, our investigators noted the following conditions on your farm.

1. Failure to maintain a system to ensure that animal drugs are used properly. Specifically, no medical treatment records are maintained, no temporary or permanent record-keeping system is in place to identify treated animals, the dates of treatment, the drug(s) administered, who administered the drug(s), the amount administered, route of administration, and the withdrawal time to be observed prior to slaughter or sale of the animals.

2. Failure to maintain a system for identifying and tracking the sale of medicated animals. Specifically, there is no system to identify medicated animals at the time of sale to ensure that the animal is withheld from slaughter for the appropriate period of time to permit depletion of potentially hazardous residues of drugs from edible tissues of animals before being offered for slaughter for human consumption.

Foods from animals held under such conditions are adulterated. Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act. It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure, and/or injunction.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If the corrective actions cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Edwin Ramos, Compliance Officer.

Sincerely,

Michael A. Chappell
Dallas District Director

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